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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/668,573
Filing Date: September 23, 2003
Appellant(s): COPPETA ET AL.

Kevin W. King
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 28 December 2007 appealing from the Office action mailed 2 July 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 4,111,202 | THEEUWES | 9-1978 |
| 5,797,898 | SANTINI ET AL | 8-1998 |

| | | |
|---|---|---|
| 7,025,323 | KRULEVITCH ET AL | 4-2006 |
| 6,692,456 | EPPSTEIN ET AL | 2-2004 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 14-18,20-29, 35,36, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Eppstein et al (US 6,692,456).

Eppstein teaches an array of discrete microtubes (a, Fig 23a and 23b), each defining a reservoir (b, Fig 24), a release formulation wholly contained within the reservoir (Fig 24), a rupturable covering (c, adhesive or thin film backing, Col 31 line 38), and means for rupturing the covering/barrier material (e, thermal poration element) and positively displacing the release formulation (pressure modulation activation linkages, Fig 23a and 23b, activated by a small pump, Col 29 lines 45-55). As to claim 15, the walls of the reservoir create defects were the thin film backing is attached; .as to claims 16-18,20, the expanding material (e expands when it is exploded into a gas and the pressure modulation linkages expand under the pressure created by the pump, see Fig 22a-d) is

activated by heat (see Col 6 line 58-Col 7 line 10). As to claim 21, Col 11 line 43; claim 24, see claim 7; claim 27, Col 19 line 44; as to claim 28, this claim is a product-by-process claim and is given little patentable weight as it must result in a structural difference between the prior art and the invention; claim 29, Fig 25; claim 39, see claim 46.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 19 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al (US 7,025,323) in view of Santini Jr et al (US 5,797,898).

Krulevitch teaches an array of discrete microtubes (97) defining a reservoir (86-90), a release formulation (103), and means for dispensing the release formulation (81-85) by positive displacement of a barrier material (98-102) by an expanding material (81-85) by application of heat from a resistive heating element (81'-85'). See Figs 7A and 7B. Krulevitch does not disclose the material of the microneedles being made of a metal, or a rupturable metal foil covering over the distal end of the microneedles.

Santini discloses a microreservoir array which is covered by a metal foil where the array is made of a biocompatible material (copper or gold, for example). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a metallic cover over the microneedles in order to prevent leakage of the reservoirs or

contamination of the reservoir contents. Regarding claim 20, copper is considered "reactive." Regarding the defects to facilitate rupture, the bonding of the metal layer would inherently create stress concentrations in the metal foil along the edge of the microneedle. Claim 28 is a product by process claim which is given little patentable weight.

3. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein as applied to claims 14 and 16 above, and further in view of Theeuwes (US 4,111,202).

Eppstein teaches the limitations of claim 16 as above, but do not teach the use of a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation. Eppstein teaches that a "small pump" may be used to supply the expanding means.

Theeuwes teaches an osmotic drug delivery system with a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation (Fig 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the osmotic delivery system of Theeuwes as an alternate "small pump" with the micro needle array of Eppstein in order to facilitate expansion of the expandable member without electronics.

**(10) Response to Argument**

**Ground No. 1: Eppstein**

Applicant argues that Eppstein's device does not positively displace the fluid from the reservoir. Applicant argues that the space occupied by fluid in the reservoir be eliminated or that the fluid be pushed out by another material. This is not fond in the claims or the phrase "positively displacing the release formulation." As seen in Eppstein, the entire reservoir is displaced downwards under the force of a small pump to expel the release formulation from the reservoir.

Applicant next argues that Eppstein does not teach a means for rupturing and positively displacing." Applicant use of means-plus-function language in the claims is open-ended because the specification gives no explicit definition of what the "means" or their equivalents are. The applicant's uses terms like "such as" or "for example" when describing the means and therefore any structure which performs the same function is an equivalent. Eppstein provides a means for rupturing (e) and means for displacing (linkages). The examiner has reasonably construed the means to be two separate means, not a single means as the applicant argues. The applicant has not claimed or limited the means-plus-function language to be a *single* means for performing two functions.

**Ground No. 2: Krulevitch in view of Santini**

Applicant has argued that the microneedles do not contain a reservoir of release formulation. The microneedles are hollow, defining a cylindrical reservoir therein, and some of the release formulation is contained within the microneedles. Further supporting the examiner's position is the amendments made to claim 14 that the release

formulation is "wholly contained" within the microtube, versus claim 19 which does not require the release formulation to be wholly contained in the microtube.

Applicant then argues that it would not be obvious to combine the covering of Santini with the microneedles of Krulevitch. Krulevitch teaches a system using hydrophilic and hydrophobic interactions to prevent the drug from leaking out of the reservoir. This is limits the device to charged drugs, and does nothing to prevent contaminants from entering the reservoir. Santini's covering would both prevent contamination and allow a wider range of drugs to be delivered. One of ordinary skill in the art would recognize both of these advantages and would combine the delivery mechanism of Krulevitch and the covering of Santini in order to overcome the drawbacks of Krulevitch alone.

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**Ground No. 3: Eppstein in view of Theewues**

Applicant has argued that removing electronics is not a reason to modify the device of Eppstein. Eppstein teaches that a "small pump" may be used to activate the pressure modulation linkages (Col 29 lines 45-55). Theewues teaches an osmotic pump, which is a species of the genus "small pump." One of ordinary skill in the art would recognize that an osmotic pump is easily substituted for a "small pump" and that an osmotic pump does not require electronics, which may simplify its design.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elizabeth MacNeill

/Elizabeth R MacNeill/

Examiner, Art Unit 3767

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TC3700 TQAS